

### Remarks

Claims 27-44 are pending. Claims 1-18 have been canceled. Claims 27-40 have been amended. Support for the claim amendment can be found throughout the application, including the claims as originally filed. Importantly, no new matter has been added to the claims. Further, the amendments to the claims should not be construed to be an acquiescence to any of the rejections. The amendments to the claims are being made solely to expedite the prosecution of the instant application. Applicant expressly reserves the option to prosecute further the same or similar claims in the instant application or subsequent patent applications entitled to the priority date of the instant application. 35 USC § 120.

### Claim Rejections Based on 35 USC § 112¶1

In paragraph 3, the Examiner rejects claims 1-18 and 27-44 as failing to comply with the written description requirement for reasons of record since  $R_{15}$ ,  $R_{16}$ ,  $Q_1$  and  $Q_2$  as defined are not described in the specification.

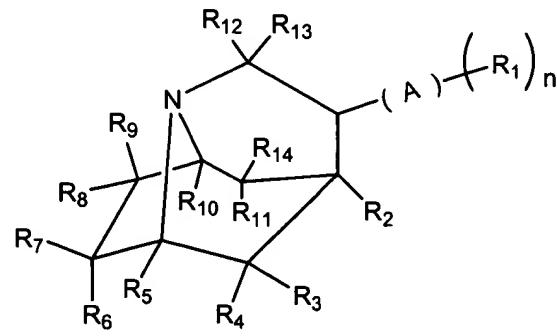
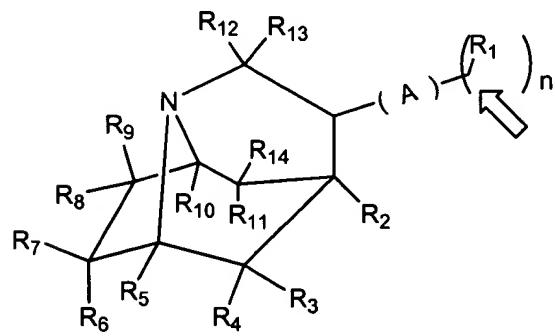
The Applicants would like to remind the Examiner that these terms were introduced in the previous response to address a 35 U.S.C. § 112¶2 rejection made by the Examiner in an Office Action, issued September 9, 2002. In that Office Action, the Examiner referred to the various groups acyl, ether, sulfonyl, carbonyl, phosphoryl, amido, ester, *etc.* as “bivalent” even though it should be clear from formula I in claims 1, 7, 11, 27, 33, and 37 that the rules of valence require them to be monovalent groups bonded to the tropane framework. While the Examiner and Applicant now agree that “it is clear that they [*i.e.* the functional groups in question] are attached to the tropane core,” she still argues that the Applicants must indicate where in the specification there is support for the “additional group to be attached thereto.” The Applicants strongly disagree.

Support for the introduction of  $R_{15}$ ,  $R_{16}$ ,  $Q_1$ , and  $Q_2$  can be found in any common dictionary or organic chemistry text book. For example, in the Shorter Oxford English Dictionary (5<sup>th</sup> Edition), “ester” is defined as “any organic compound in which a hydrogen atom in an acid is replaced by an alkyl, aryl, *etc.* group”. Similar definitions

can be found online (e.g., on the BioTech web site -- <biotech.icmb.utexas.edu>; located in Dr. Andrew Ellington lab at University of Texas at Austin, BioTech is a hybrid biology/chemistry educational resource and research tool on the internet). Accordingly, the Applicants respectfully request the withdrawal of the rejections of claims 1-18 and 27-44 under 35 U.S.C. § 112 ¶1.

In paragraph 4, claims 1-4, 7-18, 27-30, and 33-44 are rejected based on the Examiner contention that undue experimentation would be required for one of ordinary skill in the art to make these highly substituted compounds, especially when the starting materials have not been disclosed. In order to expedite prosecution of the instant application, the Applicants have canceled claims 1-18 and amended claims 27-30 and 33-44 to encompass compounds of formula II substituted *only* at R<sub>1</sub>, R<sub>2</sub> and R<sub>14</sub>. In connection with the aforementioned amendment, R<sub>1</sub> and R<sub>2</sub> have been further amended to encompass only hydrogen, aryl and heteroaryl; R<sub>3</sub>-R<sub>13</sub> have been restricted to hydrogen; and in R<sub>14</sub>, “O-R<sub>17</sub>” has been replaced with “-O-R<sub>17</sub>” to correct a typographical error. Lastly, redundant restrictions in dependent claims, created by the aforementioned amendments, have also been addressed.

For the record, even though these relevant claims have been canceled in the instant application, the Applicants note that there is a typographical error in structure I of claims 1, 7, 11, 19, 23, 53, and 57. Specifically, a “bend” was inadvertently added to the structure that might suggest the presence of a methylene (-CH<sub>2</sub>-) unit between A and R<sub>1</sub>. The incorrect structure, with an arrow indicating the mistake, and the corrected version are shown below.



The Examiner also expressed some doubt as to whether compounds claimed but not prepared have the claimed activities. The Applicants respectfully submit that in accordance with *In re Brana* the Examiner may be confusing the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption. *See In re Brana*, 51 F.3d 1560, 1567 (Fed. Cir. 1995). In *In re Brana*, a compound that was structurally similar to a compound known to have a certain property was held to have the same utility even though it had not been expressly tested for those properties. The court held this view even while acknowledging that “[a]lthough it is true that minor changes in chemical compounds can radically alter their effects on the human body, *Kawai*, 480 F.2d at 891, 178 USPQ at 167, evidence of success in structurally similar compounds is relevant in determining whether one skilled in the art would believe an asserted utility. *See Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 181 USPQ 453 (CCPA 1974); *Kawai*, 480 F.2d 880, 178 USPQ 158.” *Id.* at 1566. As in *In re Brana*, the claimed/but-not-prepared compounds are structurally similar to the claimed/prepared compounds because they share the same basic framework and only differ by the pendant R<sub>1</sub>, R<sub>2</sub> and R<sub>14</sub> groups. Therefore, testing every compound covered by the present claims should not be a requirement for obtaining a patent.

In paragraph 5, the Examiner rejects claims 11-16 as failing to comply with the written description requirement. As mentioned above, claims 11-16 have been canceled solely in order to expedite the prosecution of the instant application.

Accordingly, the Applicants respectfully request the withdrawal of the claim rejections based on 35 U.S.C. § 112 ¶1.

Fees

The Applicants believe no fee is due in connection with the filing of this paper. Nevertheless, the Director is hereby authorized to charge any required fee to our Deposit Account, **06-1448**.

Conclusion

In view of the above amendments and remarks, the Applicants believe that the pending claims are in condition for allowance. If a telephone conversation with Applicant's Attorney would expedite prosecution of the application, the Examiner is urged to contact the undersigned.

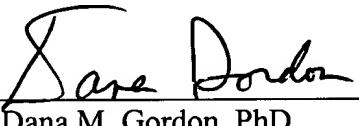
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